

CE technical file	file directory	file No.: BL-CE-06-0
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 1

No.	file chapter No.	file Name	version No.	effective date
1	BL-CE-06-0	file directory	A/0	2023-12-12
2	BL-CE-06-00	revise record	A/0	2023-12-12
3	BL-CE-06-01	manufacturer information	A/0	2023-12-12
4	BL-CE-06-02	EU representative	A/0	2023-12-12
5	BL-CE-06-03	EC conformance statement	A/0	2023-12-12
6	BL-CE-06-04	certificate	A/0	2023-12-12
7	BL-CE-06-05	product description	A/0	2023-12-12
8	BL-CE-06-06	classification	A/0	2023-12-12
9	BL-CE-06-07	product specification	A/0	2023-12-12
10	BL-CE-06-08	technical information	A/0	2023-12-12
11	BL-CE-06-0801	picture	A/0	2023-12-12
12	BL-CE-06-0802	producing procedure	A/0	2023-12-12
13	BL-CE-06-0803	component list	A/0	2023-12-12
14	BL-CE-06-0804	label	A/0	2023-12-12
15	BL-CE-06-0805	biocompatibility evaluation report	A/0	2023-12-12
16	BL-CE-06-0806	Instructions	A/0	2023-12-12
17	BL-CE-06-0807	evaluation of packaging materials	A/0	2023-12-12
18	BL-CE-06-0808	control process of production environment	A/0	2023-12-12
19	BL-CE-06-09	CE technical control	A/0	2023-12-12
20	BL-CE-06-10	test report	A/0	2023-12-12
21	BL-CE-06-11	basic requirement check list	A/0	2023-12-12
22	BL-CE-06-12	risk management	A/0	2023-12-12
23	BL-CE-06-13	standard of coordination	A/0	2023-12-12
24	BL-CE-06-14	vigilance system	A/0	2023-12-12
25	BL-CE-06-15	clinical evaluation	A/0	2023-12-12
26	BL-CE-06-16	product transportation evaluation	A/0	2023-12-12

CE technical file	revise record	file No.: BL-CE-06-00
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 2

This version has not been modified

浙江邦立医药用品有限公司
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD
童巧惠

CE technical file	manufacturer information	file No.: BL-CE-06-1
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 3

Manufacturer: Zhejiang Bangli Medical Products Co., Ltd.

Contact person: Guoli zheng

Address: No. 118, Yuegui South Road, City West New District, 321300 Yongkang city, Zhejiang Province, China

Tel: +86-579-87567541

Fax: +86-579-87567542

E-mail: bl06@ykbangli.com

CE technical file	EU representative	file No.: BL-CE-06-2
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 4

When we become a manufacturer and enter the European market, our company will mark our company name, and the name of the European delegation on our products, and provide the MDD agreement.

Name: Phoenix Medtech GmbH

Add: Koenigsberger Strasse 11, 64839, Muenster Hessen, Germany

Tel: 0049 60714977513

Fax: 0049 60717396464

Contact Person Mr. Nianzhuang Liu

Dimdi Code DE/0000049489

E-mail: contact@glgi.de

CE technical file	EC conformance statement	file No.: BL-CE-06-3
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 5

Name und Adresse des Herstellers: / Zhejiang Bangli Medical Products Co., Ltd.

Name and address of the manufacturer: / No. 118 Yuegui South Road, City West New District, Yongkang
City, Zhejiang Province 321300, China

Nom et adresse du fabricant: /

Nome e indirizzo del fabbricante:

Wir erklären in alleiniger Verantwortung, dass / We declare under our sole responsibility that /
Nous déclarons sous notre propre responsabilité que / Dichiariamo sotto la sola responsabilità che

das Medizinprodukt: / surgical tape
UMDNS-CODE:

the medical device: /
le dispositif médical: /
il dispositivo medico:

der Klasse: / I s
of class: /
de la classe: /
di classe:

nach Anhang IX der Richtlinie 93/42/EWG / according to annex IX of directive 93/42/EEC /
selon l'annexe IX de la directive 93/42/CEE / secondo l'allegato IX della direttiva 93/42/CEE

den einschlägigen Bestimmungen der Medizinprodukte-Richtlinie 93/42/EWG und deren Umsetzungen in nationale Gesetze entspricht. Die Erklärung gilt in Verbindung mit dem zum Produkt gehörigen „Endprüfprotokoll“. /

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

remplit toutes les exigences de la directive sur les dispositifs médicaux 93/42/CEE et de ses transpositions en droit national qui le concernent. La déclaration est valable si elle est associée au «rapport de l'inspection finale» du produit. /

soddisfa tutte le disposizioni della direttiva 93/42/CEE e della loro trasposizione nel diritto nazionale che lo riguardano. Questa dichiarazione è valida in congiunzione con il “rapporto di ispezione finale” del prodotto.

Konformitätsbewertungsverfahren: / **Directive 93/42/EEC Annex V**
Conformity assessment procedure: /
Procédure d'évaluation de la conformité: /
Procedura di valutazione della conformità:

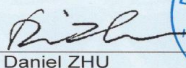
Registrier-Nr.: / **DD 60042215 0001**
Registration No.: /
N°d'enregistrement: /
Numero di registrazione:

Benannte Stelle: / **TÜV Rheinland LGA Products GmbH**
Notified Body: / **Tillystraße 2**
Organisme notifié: / **90431 Nürnberg**
Organismo notificato: **Deutschland**
CE 0197

Ort, Datum / Place, date /
Lieu, date / Luogo, data

Name und Funktion / Name and function /
Nom et fonction / Nome e funzione

CE technical file	certificate	file No.: BL-CE-06-4
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 6

	
CE Technical Documentation Review Report	
Manufacturer:	Changzhou DL Medical & Health Equipment Co., Ltd. 9 Floor, Building A, Changzhou Research Institute of Dalian University of Technology, Changzhou Science & Education Town Changzhou 213162, China
Report Number:	15096038 001
Examination intent:	Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII
Product(s):	Bandages
Type(s)/Model(s):	Kintape/Kinesiology Tapes, Elastic Adhesive Bandages, Cohesive Bandages, Sports Tapes, Elastic Bandages
Classification:	Class I, rule 1 (according to manufacturer's declaration)
Review result:	During the examination of the provided Technical Documentation (No.: DL-2011CE, Rev 02, Rev 2016-06-13), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.
Shanghai, 2016-07-29	 Daniel ZHU Lead Auditor, Product Assessment Medical Device Services 
Rev. 05, 2013-12-17	
TÜV Rheinland (Shanghai) Co., Ltd. Unternehmensgruppe TÜV Rheinland Group	TUV Building, No.177, Lane 777, West Guangzhong Road, Zhabei District, Shanghai 200072, P.R.China
Tel: (86/21) 6108 1188 Fax : (86/21) 6108 1199	e-mail : service-gc@tuv.com Internet : http://www.tuv.com

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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Zhejiang Bangli Medical
Products Co., Ltd.
No. 118 Yuegui South Road
City West New District
321300 Yongkang City, Zhejiang Province
China**

has established and applies a quality management system for medical devices
for the following scope:

**Manufacture and Distribution of Wound Plasters, Wound
Dressings, Cool Pads, Medical Tapes, First Aid Kits,
Nasal Strips, Self-adhesive Bandages, Eye Patches**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2017-11-26
Certificate Registration No.: SX 60124803 0001
An audit was performed. Report No.: 15076053 005
This Certificate is valid until: 2020-11-25

Certification Body



Date 2017-11-20



X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

CE technical file	product description	file No.: BL-CE-06-5
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 7

【product name】 pressure-sensitive adhesive tape

【size】 1cm×300cm、1.25cm×500cm、2.5cm×500cm、26cm×500cm、（Special specifications are made according to customer's needs）

【main performance】

the pressure-sensitive adhesive tape is made of banded or flaky paste material, which is divided into elastic or inelastic, and does not directly contact with the wound. sensitive adhesive tape is made from base material coated with glue, and the substrate is divided into fabric, non-woven fabric, paper, PE film and so on. The peel strength of the pressure sensitive adhesive tape is not less than 1.0N/cm, and the holding viscosity is less than 2.5mm. The permeability of the permeable pressure sensitive adhesive tape for each 24h is not less than 500g/m². Waterproofing type pressure sensitive adhesive tape should be tested at YY/T 0. The ratio between the recovery length and the full extension length of the elastic pressure sensitive adhesive tape should not be greater than 80%. No skin irritation.

【Scope of application】

The product is used to provide adhesive force for wound accessories, bandages, and so on, so as to play a fixed role.

【Usage way】

Clean the skin and dry it, and use it according to the actual needs. If the viscosity is increased, it can be properly heated and used.

【attention】

- 1、 this product is a one-time use
- 2、 water or damp should be replaced in time
- 3、 skin damage can not be used

【storage】

the pressure-sensitive adhesive tape should be stored at 0 to 30 degrees centigrade, and the relative humidity should not exceed 80%. There is no corrosive gas and well ventilated cleaning room. The height of the stacking should not exceed 1.7M.

【Expiration date】

the pressure sensitive adhesive tape after packaging is subject to the rules of storage, transportation, storage and use, and is valid for 2 years from the date of production.

CE technical file	classification	file No.: BL-CE-06-6
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 8

Medical devices have been allocated to class I s according to appendix nine of directive 93/42/EEC.
rule 1

1.1 RULE1

All non-invasive devices are in class 1, unless one of the rules set out hereinafter applies

1. Non-invasive devices

非侵入式器械

1.1. Rule 1

原则 1

All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.

除非另外适用于其他原则, 所有非侵入式器械皆属第 I 类.

CE technical file	product specification	file No.: BL-CE-06-7
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 9

Different base material: non-woven fabric, cotton cloth, Imitation cotton cloth, PE and so on.

In general speaking, the size is provided by the requirements.

Manufactured by Zhejiang Bangli Medical Products Co., Ltd.

So far, we can provide different sizes of adhesive tape. Please choose different colors according to the customer's request.

specifications	The width	The length
1 × 300	≥0.9	≥270
1.25 × 500	≥1.2	≥450
2.5 × 500	≥2.3	≥450
26 × 500	≥24	≥450
Note: special specifications are stipulated in the order contract.		

CE technical file	technical information	file No.: BL-CE-06-8
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 10

8.1 **Picture**

Appendix 8.1

8.2 **Manufacture Procedure**

Appendix 8.2

8.3 **List of components**

Appendix 8.3

8.4 **Label**

Appendix 8.4

8.5 evaluation of packaging materials

Appendix 8.5

8.6 biocompatibility evaluation report

Appendix 8.6

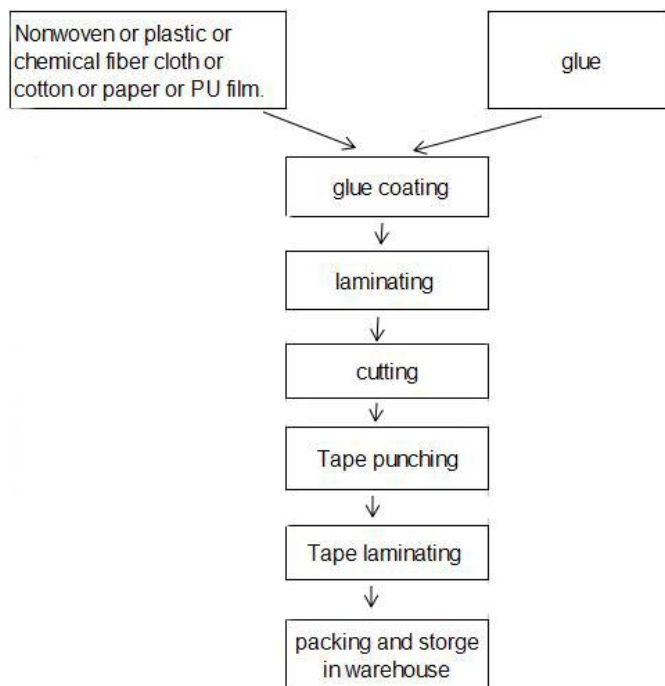
8.7 control of production environment

Appendix 8.7

Appendix 8.1 product picture



8.2 Manufacture Procedure



8.3 List of components

No.	components	supplier
1	fabric	huangzhou yangnuo
2	rubber mass	Henkel
3		
4		
5		
6		
7		

8.4 Label

8.5 biocompatibility evaluation report

EN ISO 10993-1: 2009 Biological evaluation of medical devices -
Part 1: Evaluation and testing within a risk management process:

Table 1 — Initial evaluation tests for consideration

Medical device categorization by			Biological effect							
Nature of body contact (see 4.2)		Contact duration (see 4.3)	Cytotoxicity	Sensitization	Irritation or intracutaneous reactivity	Systemic toxicity (acute)	Subacute and subchronic toxicity	Genotoxicity	Implantation	Haemocompatibility
Category	Contact	A — Limited (< 24 h) B — prolonged (24 h to 30 days) C — permanent (> 30 days)								
Surface device	Skin	A	x	x	x					
		B	x	x	x					
		C	x	x	x					
	Mucosal membrane	A	x	x	x					
		B	x	x	x					
		C	x	x	x		x	x		
	Breached or compromised surface	A	x	x	x					
		B	x	x	x					
		C	x	x	x		x	x		

The following three points need to be considered

1. Cytotoxicity
2. Delayed-type hypersensitivity
3. Irritation (including intracutaneous reactivity)

The accessories in our pressure sensitive adhesive tape are all procurement of qualified raw materials. In the 09 Certificate of Conformity product compliance certificate, there are detailed certification of the manufacturers, and the test reports of the corresponding materials. As for the factory production environment, there are corresponding strict control procedures.

sender	report No.	test product	test project	test standard	test organization	test date	Applicable range of products
Zhejiang Bangli	WT16080871	Pressure sensitive adhesive tape	skin sensitization test	GB/T16886.5-2003 GB/T16886.10-2005	State Food and Drug Administration Guangzhou medical device quality supervision and Inspection Center	2017.09.12	Pressure sensitive adhesive tape
Zhejiang Bangli	WT16080871	Pressure sensitive adhesive tape	skin irritation test	GB/T16886.5-2003 GB/T16886.10-2005		2017.09.12	Pressure sensitive adhesive tape
Zhejiang Bangli	WT16080871	Pressure sensitive adhesive tape	cytotoxicity	GB/T16886.5-2003 GB/T16886.10-2005		2017.09.12	Pressure sensitive adhesive tape

In summary, the product meets the European Union's requirements for biocompatibility.

8.6 Evaluation of packaging materials

Appendix summary:

test project	report No.	Test basis	rest result
Accelerated aging test	SDWH-PROTOCOL-M201402846	ASTM F 1980-07、 ISO11737-2: 2009	Pass
Flexible packaging leakage test		ASTM D 3078-02、ASTM D 3078-02	Pass
Leakage and leakage test of porous medical packaging seal		ASTM F 1929-12、ASTM F 1929-98	Pass
Microbiological barrier test test		ASTM F 1980-07、DIN 58953-6-2010	Pass
Sealing strength of soft barrier material		ASTM F 88-07、ASTM F 1980-07	Pass

- 1、The evaluation of packaging materials is determined by the testing center of the Institute of hygiene and environmental technology of Suzhou university.
- 2、Raw materials for packaging: the supplier of paper bags is: Anqing Yi Ren Packaging Co., Ltd.
- 3、If the supplier of the packaging material is changed, the supplier must be re confirmed.
- 4、Inspect and verify packaging materials by qualified suppliers, meet the requirements of inspection specifications.
- 5、The outer packing is made of double corrugated cardboard boxes, with middle packing and transportation according to customers' requirements. Products for medical devices, there is no precision parts, vibration in the transport process, will not affect the quality of products.

attachment :

- 1、Packaging seal verification report: BLFKYZ-201702
- 2、Package material verification report:SDWH-PROTOCOL-M201702846

8.7 Production environment evaluation

1.purpose

By strengthening the control of environmental in all parts of the company, we will create a clean and orderly for the production and processing of products, and the beautiful environment of employees' cleanliness.

enables the environment to meet the requirements of medical devices and the hygienic requirements of laws and regulations, so as to produce satisfactory products for users.

2. scope

It is applicable for production environment, facilities, personnel and sanitary management of products.

3.duty

3.1 The inspection team should at least once a month (if necessary, increase the number of times) to check and supervise the whole company's environment.

3.2 The person in charge of each workshop (Department) is responsible for the environmental work in the area

under its jurisdiction. The person in charge of the production and each process should also examine the cleaning and maintenance of each team.

3.3 Employees should be responsible for tidiness of their own and work area environment and check with each other.

3.4 All cleaners should be responsible for cleaning work in designated areas.

3.5 The inspection team and all levels of management should make a decision on the workshops, departments and members who violate the management system to rectify in a limited period of time and make suggestions to the general manager for economic punishment if necessary.

4.management procedure

4.1 material warehouse

4.1.1 Cleaners are responsible for timely cleaning of unclean warehouses caused by materials entering warehouses.

4.1.2 The warehouse keeper should keep the material in accordance with the provisions, provide the necessary storage conditions for the material storage, and keep the materials which are easily dampened and mouldy separately, so that the storage environment is controlled reliably.

4.2 workshop

4.2.1 After working, we should clean the machine, work table and so on in time, and keep it clean and tidy, clean up the detained objects in time, prevent the accumulation of dust, so as to effectively inhibit the production of mould. The raw materials, semi-finished products and finished products are positioned to ensure the cleanliness of raw materials and semi-finished products.

4.2.2 Each workshop should put the collected impurity or dirt separately into the designated site for stacking. When the equipment is overhauled, a thorough cleaning will be carried out to the workshop, and all items unrelated to production are withdrawn, and timely dust collection on the ground and cleaning of the equipment. Effective and effective removal of impurities and dirt to ensure clean environment inside and outside the workshop, no garbage, no dust, no mold.

4.2.3 The workshop should be thoroughly cleaned before production. The maintenance and inspection personnel must wear protective equipment when they enter the workshop. The ultraviolet lamp is disinfected for an hour after work every day

4.2.4 People who have direct contact with the raw materials, semi-finished products and finished products should pay attention to their personal cleanliness and hygiene. They should first change shoes, work clothes and hats before entering the workshop, and then wash hands and disinfect them and dry. It is strictly forbidden to bring food, dirt and wet things into the workshop, wipe the operating table with alcohol every day, wipe the revolving box and tool every week, and irradiate the work clothes and shoes and hats with the ultraviolet light after work every day. No spitting or littering is prohibited during work. No speech or pollution prevention is allowed.

4.2.5 The box cover should be covered on the turnover box during the production process, so as to prevent dust from attaching to the processed product and affect the quality of the product. When shutting down, doors, water, electricity and equipment should be closed, and proper maintenance should be taken if necessary to ensure the integrity of the environment and equipment, and to make adequate preparations for production.

4.2.6 The cleaner is responsible for cleaning the designated sanitary area, collecting the garbage from various workshops and departments, transporting it to the designated place, and keeping the cleanliness of the public places such as production workshops ,office hall, the factory district Avenue and so on in time.

4.3 The inside and outside of the environment of the laboratory should be neat and clean. All the instruments in use are clean and effective, and the experimental environment should comply with the requirements in working time.

4.4 The whole company's staff should maintain cleanliness and hygiene of their personal and work areas, accept supervision and inspection by all levels of management departments, and promptly correct non-conformance.

4.5 Environmental sanitation inspection

4.5.1 The head of production department or the team leader is responsible for conducting a self inspection of each class's environmental hygiene situation and making good records.filing to the administration department at the end of each month.

4.5.2 The temporary inspection of company, at each month (at least once) carries out a spot check on the environmental hygiene of the production workshop. If it does not meet the requirements, the workshop or individual shall be charged with the timely rectification and record of the results of the inspection.

4.6 Records of inspection and spot checks shall be kept by the administrative department for at least three years.

5.Related records

QR—640—01	《Equipment and environmental cleaning monthly registration form》
QR—640—02	《Workshop environment and personal hygiene check list》

CE technical file	CE file control	file No.: BL-CE-06-9
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 11

一、File control requirements

1. purpose

Controlling the documents and materials related to CE to ensure that products meet MDD93/42/EEC requirements.

2. scope

It is applicable to documents and data related to the verification of CE, including external documents and information.

3. duty

- 3.1 The quality supervision department is responsible for organizing the change control and filing management of CE documents. Under special circumstances, the document control procedure is followed in the quality management system procedure document.
- 3.2 The quality supervision department is responsible for organizing and writing CE programming documents, product introductions, compliance statements and other documents.
- 3.3 The management representative is responsible for the preparation and formulating pre-clinical research data, biocompatibility test, various product label regulations and other documents.
- 3.4 The quality supervision department is responsible for formulating the basic requirements checklist, product risk management analysis, product review, process flow, packaging and other documents.
- 3.5 The revision of CE program files and technical documents is organized and implemented by the administrative personnel department, and the representatives of the management are examined and approved by the general manager. The contents of the amendment shall be notified to the announcement organ when necessary, and the amendment should be recorded.
- 3.6 The translation of CE program files and CE technical documents and the confirmation after translation are organized by the management representatives.

二、CE technical documents are updated once a year. If there is any change, update them in time.

三、Update the clinical evaluation data and risk analysis report annually

CE technical file	test report	file No.: BL-CE-06-10
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 12

sender	report No.	test product	test project	test standard	test organization	test date	Applicable range of products
Zhejiang Bangl	WT1608087 1	Pressure sensitive adhesive tape	skin sensitization test	GB/T16886.5-2003 GB/T16886.10-2005	State Food and Drug Administration Guangzhou medical device quality supervision and inspection Center	2017.09.12	Pressure sensitive adhesive tape
Zhejiang Bangl	WT1608087 1	Pressure sensitive adhesive tape	skin irritation test	GB/T16886.5-2003 GB/T16886.10-2005		2017.09.12	Pressure sensitive adhesive tape
Zhejiang Bangl	WT1608087 1	Pressure sensitive adhesive tape	cytotoxicity	GB/T16886.5-2003 GB/T16886.10-2005		2017.09.12	Pressure sensitive adhesive tape
Beijing brilliant century industry and Trade Co., Ltd.	SHAEC1319 7991 11	Hot melt glue	The detection of cadmium, lead, mercury, six valent chromium, PBB, polybromo two phenyl ether (PBDE) is in line with the EU directive ROHS 2002/95/EC directive 2011/65/EU requirements.	IEC62321-5: 2013	SGS Standard Technical Service Co., Ltd.	2017.10.16	Pressure sensitive adhesive tape

name	Pressure sensitive adhesive tape	lot No.	20151216
size	Plain cloth, paper type, breathable type, cotton cloth type and elastic type size: 2.5cm×500cm	test purpose	record inspection
sample quantity	10	sampling base	500
test date	2015-12-16	report date	2015—12—29
inspection basis	technical requirements for pressure sensitive adhesive tape		

NO ·	stand ard term	test project	standard requirements	test result
1	2.1	appearance	the pressure sensitive adhesive tape should be rolled up, smooth and clean.	qualified
			the glue of pressure sensitive adhesive tape should be evenly coated without degumming, glue leakage and backside seeping.	
			when the breathable tape open, the stratification is not allowed.	
2	2.2	material	the base material is made of non-woven fabrics or plastic or chemical fiber cloth or cotton or paper or PE film	qualified
			Pressure sensitive adhesive used in adhesives	
3	2.3	size	size: 2.5cm×500cm width: ≥2.3cm length: ≥500cm	size: 2.5cm×500cm width: 2.5cm length: 500cm
4	2.4	peel strength	the peeling strength of the base band should not be less than 1.0N/cm。	2.8N/cm
5	2.5	Stickiness	the stickiness of the base band should not be bigger than that 2.5mm。	2.0mm
6	2.6	breathability	the permeability of breathable pressure sensitive adhesive tape in 24 hours should be less than 500g/m ²	550g/m ² 。
7	2.7	water proof type	waterproofing pressure sensitive adhesive tape should be tested at YY/T 00471.3 — 2004, that should not has Seepage phenomenon	/
8	2.8	elastic-type	the ratio between the recovery length and the full extension length of the elastic pressure sensitive adhesive tape should not be bigger than 80%.	/
9	2.9	skin irritation	no skin irritation	no skin irritation(report on the provincial medical equipment inspection institute)
test conclusion				
remark				

CE technical file	basic requirement check list	file No.: BL-CE-06-11
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 13

See Annex.

File name: Essential Requirements

Document number: BL/CE-03-ER

Version version: E/0

CE technical file	basic requirement check list	file No.: BL-CE-06-12
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 14

See Annex.

File name: Risk Analysis

Document number: BL/CE-03-RA

Version : E/0

CE technical file	standard of coordination	file No.: BL-CE-06-13
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 15

GB/T 191-2008 Package and transportation graphic sign

GB/T 2828.1-2012 count sample inspection procedure

part 1: sampling inspection plan for batch inspection according to receiving quality limit (AQL)

GB/T 2829-2002 periodic inspection sample procedures and tables (applicable to process stability test)

GB/T 16886.10-2005 biological evaluation of medical instruments

part 10 stimulation and delayed type hypersensitivity test

YY/T 0148-2006 Pressure sensitive adhesive tape common requirement

YY/T 0466.1-2009 Medical devices symbols used to label, mark and provide information for medical devices. part 1: common requirement

CE technical file	vigilance System	file No.: BL-CE-06-14
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 16

1.purpose

this procedure is aimed at the warning system of all products. Corrective measures are to make the quality out of control change to quality control, and quality improvement is to improve the quality under controlled conditions.

2.scope of application

applicable to all product requirements

3.duty

The sales department is the centralized management department of this procedure, and is responsible for establishing a document feedback system.

the quality inspection department and the production department participating in the whole process of warning system's corrective measures

other relevant departments work with the vigilance system

4.control procedure

4.1 information input

4.1.1the system can give early alarm from internal and external quality problems of the supplier, and can enter the corrective or preventive measures system.

4.1.2record all customer complaints' record

4.1.2.1customer complaint form: written, telephone, oral, etc.

4.1.2.2 customer complaint content:

a.the products do not meet technical standards or customer requirements.

b.Product name (specification, lot number)

c.receipt of the date of complaint

d.name and address of the complainant

e.the nature of the complaint

4.2 information out put

4.2.1 When the disqualified products have been sold are potentially harmful to the user or violate the rules and regulations, it is necessary to decide whether it is necessary to send a notice of advice, to carry out the product recovery and to report the local or national authorities according to the extent of injury or violation of the regulatory requirements.

4.2.2 procedure content

4.2.2.1 The supplier determines the sending of the coordinative advisory notice by the authorized person, and the recovery of the product.

4.2.2.2 Even if the key personnel are absent, there are management arrangements that enable the operation of this procedure.

4.2.2.3 Clearly adopt corrective measures and improve imperfect production methods

4.2.2.4 Deciding how to return products, such as rework, repackaging, scrapping, etc.

4.2.2.5 Report to local or national authorities when necessary.

4.2.2.6 Identify and establish a communication system for information and liaison between national authorities

4.3 Advice or product response is provided below content:

- a. Description of product, batch number, production date, team, inspection and so on.
- b. The reasons for sending advice and product recovery
- c. Possible harm notifications and subsequent measures
- d. The process of recovery should be monitored and the number of products received should be same by consultation.
- e. The supplier shall establish and maintain written procedures for announcements of product notices, and can perform these programs at any time.

4.4 Corrective measures

4.4.1 Effectively handle customer comments and product failure reports.

4.4.1.1 Customers' opinions, complaints and appeal should be emphasized. The customer's opinion is not the product that has not met the requirements, but it does not meet the customer's expected use or reasonable expectations, so the customer complaint should be taken seriously.

4.4.1.2 The seriousness of the quality problems in the disqualification report should be evaluated, that is, the extent of the potential impact on the quality of products, such as processing cost, quality cost, performance, credibility, safety and customer satisfaction, to evaluate the severity of the impact on the quality of the product

4.4.2 Investigate the causes of disqualification related to the production process and quality system and record the result.

4.4.3 Identify corrective actions, that is, through careful analysis of the root causes or various reasons leading to unqualified products. Based on product related processes, operations, quality reports and customer opinions.

5. related files

BL/QSP-423-01	《file control procedure》
BL/QSP-424-01	《quality record management procedure》
BL/QSP-560-01	《management review procedure》
BL/QSP-822-01	《internal audit procedure 》
BL/QSP-824-01	《measurement and control management procedure》
BL/QSP-830-01	《unqualified products control procedure》
BL/QSP-850-02	《customer complaint and withdrawal procedure》

6. related record

QR-850-02	《customer complaints and processing records》
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CE technical file	clinical evaluation	file No.: BL-CE-06-15
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 17

Clinical assessment report

pressure-sensitive adhesive tape

According to the: MEDDEV 2.7/1 revision 4

Preparation:

Approval:

Version: 01

1. Equipment overview:

Name: pressure-sensitive adhesive tape

Model: The company adhesive strip: nonwoven fabric, The isolation of paper

Manufacturer: Zhejiang Bangli Medical Products Co., Ltd.

2. Description of equipment and intended use.

2.1. Device description: the safety classification of MDD 93/42/EEC belongs to the passive medical device of class I. Contact with human skin during the use of the instrument is a short time contact device. This instrument is a sterile instrument, only for single use, disposable consumables, not reusable.

The main components of the apparatus are: the product is used to provide adhesive force for the raw materials, bandages and so on, so as to play a fixed role.

The base material is non-woven or plastic or chemical fiber or cloth or paper or PE film. Base materials are non-woven or plastic or ciliate or cotton or paper or PE film.

The adhesive USES pressure sensitive adhesive (hot melt adhesive). The adhesive USES pressure - sensitive adhesive, hot melt adhesive).

2.2 intended use:

The product is used to provide adhesive force for the materials, bandages and so on.

3.1 Risk analysis

The risk analysis was conducted by us according to EN ISO 14971:2012 standards. The following risks were identified and the control measures were defined. Most of the risks identified were controlled

the product design or the label design, at the same time were confirmed by the product testing done by the 3rd party lab. To ensure the risk points to be addressed in the clinical implementation. We conduct the literature research for the following points.

Form 1 Risk Analysis

Types	No.	Possible Adverse Effect	Addressed by design
Biological hazards, chemical hazards, danger because of material aging.	H1	If the material is not safe will cause the user/ patient to be in danger.	The testing has been done according to EN ISO10993 series standard. Controlled as <purchasing procedure>.
	H2	If the product is contaminated will cause the user/patient to be in danger.	Sterilization validation.
Information hazards	H3	Inadequate labeling cause failure to get the right information	Control the package material as <Purchasing procedure>
Use hazards	H4	Didn't check whether the package was damaged before using	Packaging verification report. (SDWH-PROTOCOL-M201402846) Product final inspection.
	H5	Out of date use	Product acceleration aging validation report. (SDWH-PROTOCOL-M201402846) Product final inspection.

3.2 Literature search strategy

3.2.1 The literature research objective

From the risk analysis report, we may find the main concerns of this product are:

- Material safety
- Product performance

So the literature research we are planning is to address the concern above, to ensure the benefit are significant more than the risk.

3.2.2 The literature research methods

We conduct the search the database Pubmed/ Wanfang by using the keywords “first aid bandage”, “adhesive bandage” etc.

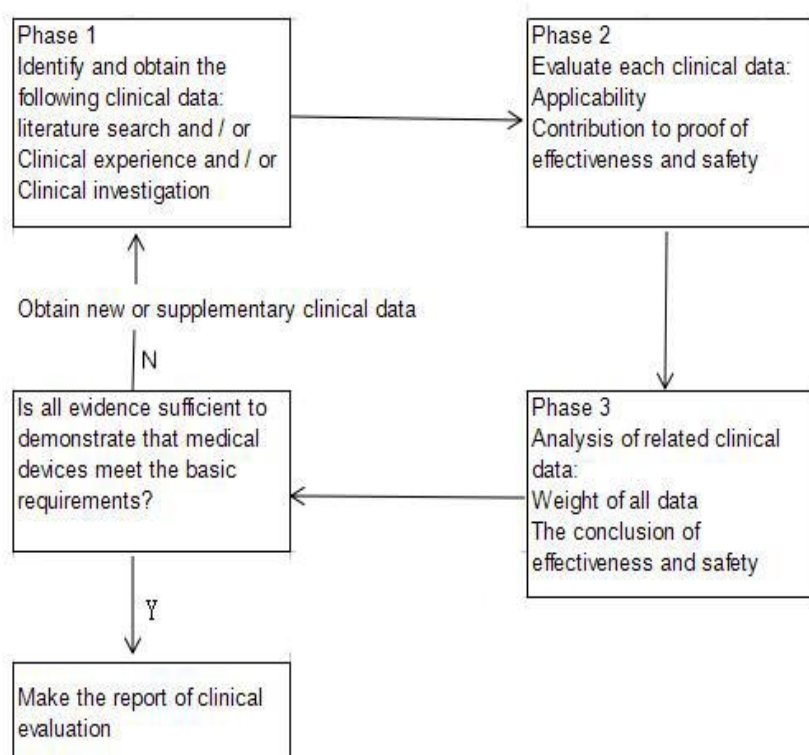
4. Selection of clinical evaluation background and clinical data type.

4.1 product development background.

It is widely used in the world, and it began to be produced in China in the 1980s and used in clinic and family. Therefore, it has a mature production process. The company has been producing sterile band-aids since 1998, passed the registration approval of the pharmaceutical management department, and passed the certification of China ISO 9001:2000 quality management system. After the past few years of development, the company's production process tend to be more mature and perfect, reliable quality, moreover, we also develop and implement the quality assurance plan, the product quality conforms to the Chinese medical devices standards ISO 13485:2016 standard requirements.

4.2 overview of the evaluation stage.

The clinical evaluation stage is divided and evaluated according to the following flowchart:



Meeting the requirements of the coordination standard can be considered to meet the relevant basic requirements.

4.3 literature search shall be conducted according to the following agreement:

A). Scope of document retrieval: literature on Corn stick.

Method b).

(1) document retrieval date: 2014-9-12.

(2) literature searcher:.

(3) retrieval covering time range: from 2001 to 2014.

(4) literature sources:

Wikipedia 2. Baidu encyclopedia 3.

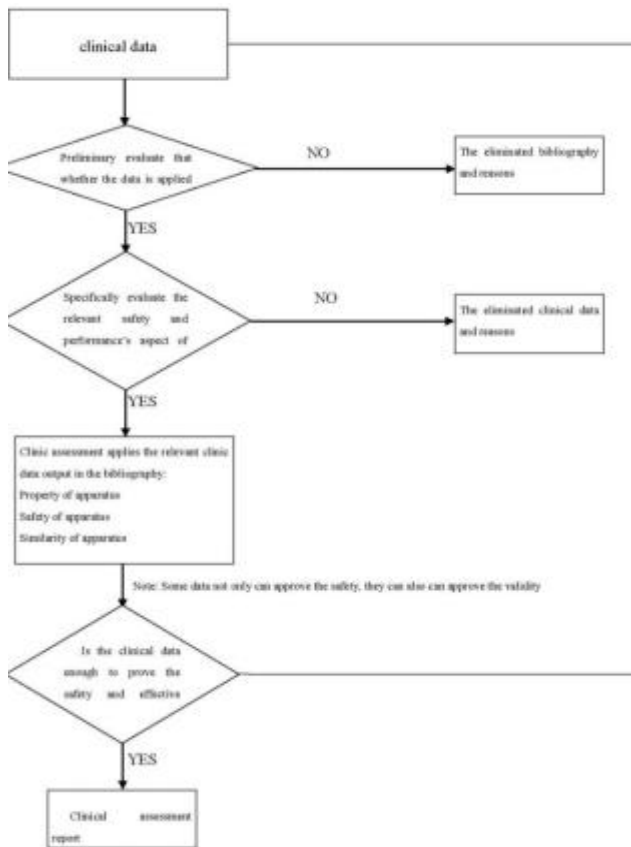
4. Others.

(5) literature retrieval details.

Search keywords: Corn stick.

Use media: computer networks, third party LABS.

(6) selection criteria of literature data: preliminary screening based on the correlation between the content of the literature and the scope of clinical evaluation.



Procedure 1

Applicable standards	describe	Grading system
Proper equipment	Is the data generated from the proposed instrument?	D1 actual instrument
		D2 equal instrument
		D3 other equipment
Proper use of equipment.	Is the intended use of the apparatus the same? (such as regulation method, application, etc.)	A1 homology
		A2 nuance
		That's a big difference
Appropriate patient population	Is the patient group that collected data expected to use the population (such as age, gender, etc.) and the medical environment (such as disease including state and severity)?	P1 applicable
		P2 partial application
		P3different
Select report/data collation.	Does the report or data include enough information to make a rational and objective assessment?	R1High quality
		R2A small amount of defects
		R3Insufficient information

table (1)

Output.

(1) a copy of the reference retrieval document is attached (see attachment)

(2) data selection process.

Attach a flowchart related form to illustrate how the reference material is evaluated and used as a clinical evaluation.

Literature retrieval output: the relevant search literature related to pre-evaluation content is as follows:

5. Clinical data and evaluation summary.

5.1 applicability evaluation

Based on the content of Wound Dressings evaluation and the document retrieval protocol, the initial applicability of the documents retrieved through process (1) and table (1) was identified.

5.2 data contribution rate evaluation.

The preliminary selection of the data is based on table (2) to provide the contribution rate to the content of the proposed evaluation.

Evaluation content	references	The data source	describe	Grading system
1. The product effect assessment	Corn stick design and use of the method	Wanfang medical network	Is the data generated from the proposed instrument?	■D1 simulates the apparatus.
				□D2 equivalent instrument
				□D3 other
2.Biological compatibility evaluation	Biocompatibility report.	Testing institutions	Is the data generated from the proposed instrument?	□D1 simulates the apparatus.
				■D2 equivalent instrument
				□D3 other
3Residual risk and potential risk assessment.	Risk management report	Our company	Is the data generated from the proposed instrument?	■D1 simulates the apparatus.
				□D2 equivalent instrument
				□D3 other

table (2)

6 Data analysis

6. 1 evaluation of data contribution rate.

Evaluation content	references	The data source	describe	Grading system
1. The product effect assessment	Corn stick design and use of the method	Wanfang medical network	Is the data generated from the proposed instrument?	■D1 simulates the apparatus.
				□D2 equivalent instrument
				□D3 other
2.Biological compatibility evaluation	Biocompatibility report.	Testing institutions	Is the data generated from the proposed instrument?	□D1 simulates the apparatus.
				■D2 equivalent instrument
				□D3 other
3Residual risk and potential risk assessment.	Risk management report	Our company	Is the data generated from the proposed instrument?	■D1 simulates the apparatus.
				□D2 equivalent instrument
				□D3 other

Based on the above clinical data analysis, the retrieved data were evaluated for the product effect, biological compatibility and residual risk of Wound Dressings, and the product performance was safe and reliable. Through suitability evaluation and the evaluation of the clinical application of part of the retrieval of literature, and consistently proved significantly Wound Dressings full performance to identify the most can prove that the performance of devices, the clinical application of the data from the hospital, scientific research and application analysis, so the literature has statistical significance, clinical importance and the consistency of results

6.3 security

The materials used in the product are both traditional materials and have a long history with the use of chicken eye stickers. It has been fully proved that it will not cause harm to the human body when used correctly.

6.4 product documentation and instructions.

Based on the relevant standards and regulations, and based on the characteristics of the product, the application instructions, label identification and other documents are prepared and analyzed and evaluated in the risk management.

7 the conclusion

On the basis of the above analysis and evaluation, the safety and performance of pressure-sensitive

adhesive tape have satisfied the intended use of the products claimed by the company. The risks associated with the use of the instrument are acceptable in the context of risk assessment and clinical evaluation.

CE technical file	Product transportation evaluation	file No.: BL-CE-06-16
		version: A/0
ZHEJIANG BANGLI MEDICAL PRODUCTS CO., LTD.		page: 18

1、Transportation evaluation procedure:

1.1 The transport evaluation is held by the management representative, the contents include as below.:

1.1.1 Evaluation of the mode of product transportation

1.1.2 Evaluation of the impact of transport on product packaging and loading and unloading of products during transportation.

2、Evaluation of transportation methods:

2.1 The means of transportation of the products are transported by car to the shipping warehouse, loaded into containers and transported by sea.

2.2As the car is the best way to transport, the car is equipped with a fixed product rope and rain prevention by rain cloth and other tools, with the above method can meet the transportation needs of our products.

2.3Another way of transportation is express delivery. It can also meet the demand for transportation

3、Evaluation of transportation tools and loading and unloading:

3.1transportation tools

The transport company of the product is a strictly screened qualified transport supplier whose transport tools are regularly maintained to prevent the product from affecting the product due to the problem of transportation.

3.2Loading and unloading

The loading and unloading of the product is carried out by the qualified handling company selected by the company to carry out the civilized loading and unloading, light load and light unloading. The product is in conformity with the transportation requirements of the product after the "carton packing test".

4、Conclusion of transportation evaluation :

The mode of transportation of the product is evaluated and accorded with the relevant requirements of the product. The mode of transportation is reasonable and feasible, and can be used in the usual production process.

5、Record

Report on packaging and carrying test BL/CE-03 BZY2017001

Evaluation and verification scheme for packaging materials of medical instruments

Formulate:

Approval:

Stacking Test

sample name: Pressure sensitive adhesive tape

test date: 2017.8.18-2017.8.25

test basis: Refer to GB/T 4857.1-92, GB/T 4857.3-2008 method

test way:

- 1.The sample is placed on the horizontal plane according to the predetermined condition, so that the loading packaging assembly is placed on the top surface of the sample and stacked with 6 layers, total 18 CTNS
- 2.The duration of the maintenance of the load is 1 weeks
- 3.Remove the load and check the test product

result: 18 CTNS were extracted and tested respectively, the result as below

sample No.	size	carton	inner packing	sample	determine
1	no change	no damage	no damage	intact	qualified
2	no change	no damage	no damage	intact	qualified
3	no change	no damage	no damage	intact	qualified
4	no change	no damage	no damage	intact	qualified
5	no change	no damage	no damage	intact	qualified
6	no change	no damage	no damage	intact	qualified
7	no change	no damage	no damage	intact	qualified
8	no change	no damage	no damage	intact	qualified
9	no change	no damage	no damage	intact	qualified
10-18	no change	no damage	no damage	intact	qualified



Conclusion: after testing, the packaging of the products has not changed in size, the cartons are in good appearance, the inner packaging products are intact, and the products are intact.
the product can be stacked at a height of not more than 6 layers, it has no effect on the product, and all products can be stacked at a height of 6 stories.

test finished date: 2017.8.25

test person:

Auditor:

Drop test

sample name: Pressure sensitive adhesive tape

test date: 2017.8.25

test basis: Refer to GB/T 4857.1-92、GB/T 4857.2-92、GB/T4857.5--92 method

test way:

- 1.Numbering the parts of the sample according to the requirements of GB/T 4857.1-92
- 2.Bring up the sample to the height of 1.8m, and fix it according to the predetermined condition.
- 3.Release the sample and let it fall freely
- 4.Check the damage of the sample and analyze the result

result:

	face 1	face 2	edge 1	edge 2	Side 1	side 2	inner packin g	sample	determine
1	no damage	no damage	no damage	no damage	no damage	no damage	no damage	intact	qualified
2	no damage	no damage	no damage	no damage	no damage	no damage	no damage	intact	qualified
3	no damage	no damage	no damage	no damage	no damage	no damage	no damage	intact	qualified
4	no damage	no damage	no damage	no damage	no damage	no damage	no damage	intact	qualified
5	no damage	no damage	no damage	no damage	no damage	no damage	no damage	intact	qualified

Before the test:



Test height: the effective height is more than 2 meters.

After falling, the products are intact, and the packaging and products are not damaged.

Conclusion:

The sample has fallen through the above conditions. After testing, the packing box and the product are still in good condition, indicating that the product has excellent anti dropping performance. It also indicates that the product can be kept in good condition during transportation.

test finished date: 2017.8.25

test person:

Auditor: